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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,086	11/21/2003	Brad S. Culbert	TRIAG-001A	2258

7590

11/16/2004

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EXAMINER

DAVIS, DANIEL J

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 10/719,086	Applicant(s) CULBERT, BRAD S.	
	Examiner D. Jacob Davis	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9,12-14,21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 is/are allowed.
- 6) ☒ Claim(s) 1-7,9,12-14 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,123,711 to Winters in view of U.S. Patent No. 6,231,606 to Graf et al. Winters discloses a soft tissue anchor device (Figs. 1-3) comprising an elongate body 20, a helical anchor 212, a retention structure 222, a proximal anchor 31, and an adjustable flange 40. The adjustable flange itself is *configured* to receive at least the tip of the proximal anchor 31. As illustrated in Fig. 1, there is a gap 41 between the adjustable flange 40 and the proximal anchor 31. The gap allows the adjustable flange 40 to be positioned at a variable angle.

The device further comprises a plurality of spikes 44 that may be spaced around perimeter of the flange and equidistant from one another (Figs. 2B and 2C). The gap 41 is considered a flange recess 41, which is configured to engage an installation tool. In theory the proximal anchor may be "split" into two portions, a proximal and a distal.

Winters further discloses that the proximal anchor has a rounded outer surface portion 32. However, Winters fails to disclose a fastener having a spherical head (not

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claimed in the instant application) and an adjustable flange 40 that has a spherically recessed portion. Nevertheless, Graf teaches a fastener having a spherical head and a spherical recessed portion permitting free angulation of the fastener in a low profile manner.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a spherical recess within Winters' flange 40, and to make the fastener head spherical, permitting free angulation of the fastener in a low profile manner.

Winters also fails to disclose that the device may be made of titanium. Nevertheless, Graf teaches the device may be made from titanium (column 2, lines 54-56). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the elongate body out of titanium because of its light weight and biocompatible nature.

Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,123,711 to Winters in view of U.S. Patent No. 6,231,606 to Graf et al. in further view of U.S. Patent No. 4,988,351 to Paulos et al.

Winters is silent regarding the dimensions of the elongate member. Nevertheless, Paulos discloses a threaded fastener and washer device for attaching soft tissue to bone having the fastener dimensions as specified in claims 12-14 (Paulos, col. 3, lines 18-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the Winters device having the

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dimensions specified by Paulos in order to effectively attach the threaded fastener within the bone.

Allowable Subject Matter

Claim 8 is allowed.

Response to Arguments

Applicant's arguments filed September 16, 2004 have been fully considered but they are not persuasive. Winters discloses a proximal anchor having a rounded outer surface portion permitting the anchor 20 to be anchored at various angles with respect to the flanged 40. Furthermore, as cited by applicant, Winters does not disclose that the adjustable flange has a spherically recessed portion. Nevertheless, Graf cures this deficiency.

Applicant proposes that modifying the Winters flange could create stresses that weaken and break the flange. Understandably, a design change could alter the strength of the flange to some unknown degree. However, even if such a design change decreases the strength of the flange to the point of breaking, this does not obviate the motivation for altering the Winters flange. Moreover, established engineering principles may be used to compensate for a design weakness such as a change in material, shape, or size.

As stated, the rounded head 32 disclosed by Winters permits the anchor to be positioned at various angles. Were this not Winters' intention, surely a flat head would

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have been the logical choice to create a low profile and minimize tissue damage. As pointed out by applicants, the gap 41 does not illustrate the correct relative dimensions of the gap 41 relative to the head 32. Nonetheless, a gap is illustrated, and any gap would permit some change in angle. Therefore, it is concluded that the anchor is permitted to be angled with respect to the flange (or vice-versa).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: U.S. Des. No. 374,287 to Goble et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Jacob Davis whose telephone number is (571) 272-4693. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DJD


DAVID O. REIP
PRIMARY EXAMINER